

Alkermes plc.
Form 10-Q
November 01, 2012
[Table of Contents](#)

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2012

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Commission File Number 001-35299

ALKERMES PUBLIC LIMITED COMPANY

(Exact name of registrant as specified in its charter)

Edgar Filing: Alkermes plc. - Form 10-Q

Ireland

(State or other jurisdiction of incorporation or organization)

98-1007018

(I.R.S. Employer Identification No.)

Connaught House

1 Burlington Road

Dublin 4, Ireland

(Address of principal executive offices)

+ 353-1-772-8000

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days: Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files): Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act:

Large accelerated filer ☐

Accelerated filer ☐

Non-accelerated filer ☒

Smaller reporting company ☐

(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act): Yes ☐ No ☒

The number of shares of the issuer's ordinary shares, \$0.01 par value, outstanding as of October 26, 2012, was 131,930,050 shares.

Table of Contents

ALKERMES PLC AND SUBSIDIARIES
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2012

		Page No.
	<u>PART I - FINANCIAL INFORMATION</u>	
<u>Item 1.</u>	<u>Condensed Consolidated Financial Statements:</u>	
	<u>Condensed Consolidated Balance Sheets September 30, 2012 and March 31, 2012</u>	3
	<u>Condensed Consolidated Statements of Operations and Comprehensive (Loss) Income</u>	
	<u>For the Three and Six Months Ended September 30, 2012 and 2011</u>	4
	<u>Condensed Consolidated Statements of Cash Flows For the Six Months Ended</u>	
	<u>September 30, 2012 and 2011</u>	5
	<u>Notes to Condensed Consolidated Financial Statements</u>	6
<u>Item 2.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of</u>	
	<u>Operations</u>	19
<u>Item 3.</u>	<u>Quantitative and Qualitative Disclosures about Market Risk</u>	29
<u>Item 4.</u>	<u>Controls and Procedures</u>	30
	<u>PART II - OTHER INFORMATION</u>	
<u>Item 1.</u>	<u>Legal Proceedings</u>	31
<u>Item 1A.</u>	<u>Risk Factors</u>	31
<u>Item 2.</u>	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	31
<u>Item 5.</u>	<u>Other Information</u>	31
<u>Item 6.</u>	<u>Exhibits</u>	31
<u>Signatures</u>		32
Exhibit Index		
Ex-31.1 Section 302 Certification of Chief Executive Officer		
Ex-31.2 Section 302 Certification of Chief Financial Officer		
Ex-32.1 Section 906 Certification of Chief Executive Officer and Chief Financial Officer		

[Table of Contents](#)**PART I. FINANCIAL INFORMATION****Item 1. Condensed Consolidated Financial Statements:****ALKERMES PLC AND SUBSIDIARIES****CONDENSED CONSOLIDATED BALANCE SHEETS****(unaudited)**

	September 30, 2012 (In thousands, except share and per share amounts)	March 31, 2012
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 132,418	\$ 83,601
Investments short-term	67,033	106,846
Receivables	101,998	96,381
Inventory	40,887	39,759
Prepaid expenses and other current assets	12,583	12,566
Total current assets	354,919	339,153
PROPERTY, PLANT AND EQUIPMENT, NET	295,374	302,995
INTANGIBLE ASSETS, NET	596,864	617,845
GOODWILL	92,740	92,740
INVESTMENTS LONG-TERM	8,726	55,691
OTHER ASSETS	21,924	26,793
TOTAL ASSETS	\$ 1,370,547	\$ 1,435,217
LIABILITIES AND SHAREHOLDERS EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	\$ 58,406	\$ 79,154
Deferred revenue current	3,582	6,910
Long-term debt current	6,750	3,100
Total current liabilities	68,738	89,164
LONG-TERM DEBT	363,847	441,360
DEFERRED REVENUE LONG-TERM	8,845	7,578
DEFERRED TAX LIABILITIES LONG-TERM	33,568	34,512
OTHER LONG-TERM LIABILITIES	10,541	8,751
Total liabilities	485,539	581,365
COMMITMENTS AND CONTINGENCIES (Note 15)		
SHAREHOLDERS EQUITY:		
Preferred stock, par value, \$0.01 per share; 50,000,000 shares authorized; zero issued and outstanding at September 30, 2012 and March 31, 2012, respectively		
Ordinary shares, par value, \$0.01 per share; 450,000,000 shares authorized; 131,805,348 and 130,212,530 shares issued; 131,567,817 and 130,177,452 shares outstanding at September 30, 2012 and March 31, 2012, respectively	1,315	1,300
Treasury stock, at cost (237,531 and 35,078 shares at September 30, 2012 and March 31, 2012, respectively)	(3,894)	(571)

Edgar Filing: Alkermes plc. - Form 10-Q

Additional paid-in capital	1,409,562	1,380,742
Accumulated other comprehensive loss	(2,795)	(2,713)
Accumulated deficit	(519,180)	(524,906)
Total shareholders' equity	885,008	853,852
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 1,370,547	\$ 1,435,217

The accompanying notes are an integral part of these condensed consolidated financial statements.

Table of Contents**ALKERMES PLC AND SUBSIDIARIES****CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE (LOSS) INCOME****(unaudited)**

	Three Months Ended September 30,		Six Months Ended September 30,	
	2012	2011	2012	2011
	(In thousands, except per share amounts)			
REVENUES:				
Manufacturing and royalty revenues	\$ 107,327	\$ 54,039	\$ 245,707	\$ 102,979
Product sales, net	15,192	9,887	27,564	19,573
Research and development revenue	1,459	8,052	2,946	11,309
Total revenues	123,978	71,978	276,217	133,861
EXPENSES:				
Cost of goods manufactured and sold	41,491	17,530	83,561	33,749
Research and development	35,088	28,160	72,894	56,210
Selling, general and administrative	31,428	36,234	61,212	67,731
Amortization of acquired intangible assets	10,547	1,817	20,981	1,817
Total expenses	118,554	83,741	238,648	159,507
OPERATING INCOME (LOSS)	5,424	(11,763)	37,569	(25,646)
OTHER (EXPENSE), NET:				
Interest income	216	383	515	885
Interest expense	(22,648)	(7,561)	(32,818)	(7,561)
Other income, net	723	336	1,646	425
Total other (expense), net	(21,709)	(6,842)	(30,657)	(6,251)
(LOSS) INCOME BEFORE INCOME TAXES	(16,285)	(18,605)	6,912	(31,897)
INCOME TAX PROVISION	422	3,650	1,186	3,596
NET (LOSS) INCOME	\$ (16,707)	\$ (22,255)	\$ 5,726	\$ (35,493)
(LOSS) EARNINGS PER ORDINARY SHARE:				
Basic	\$ (0.13)	\$ (0.22)	\$ 0.04	\$ (0.36)
Diluted	\$ (0.13)	\$ (0.22)	\$ 0.04	\$ (0.36)
WEIGHTED AVERAGE NUMBER OF ORDINARY SHARES OUTSTANDING:				
Basic	131,067	102,474	130,753	99,578
Diluted	131,067	102,474	135,589	99,578
COMPREHENSIVE (LOSS) INCOME:				
Net (loss) income	\$ (16,707)	\$ (22,255)	\$ 5,726	\$ (35,493)
Unrealized gains (losses) on marketable securities, net of tax:				
Holding gains (losses), net of tax of none in the three and six months ended September 30, 2012 and \$111 and \$202 in the three and six months ended September 30, 2011, respectively	567	(188)	426	341
Less: Reclassification adjustment for gains included in net (loss) income	(1,030)		(1,030)	
Unrealized (losses) gains on marketable securities	(463)	(188)	(604)	341
Unrealized gains (losses) on derivative contracts:				
Unrealized losses on derivative contracts		(244)	(72)	(244)
	594		594	

Edgar Filing: Alkermes plc. - Form 10-Q

Less: Reclassification adjustment for losses included in
net (loss) income

Unrealized gains (losses) on derivative contracts		594		(244)		522		(244)
COMPREHENSIVE (LOSS) INCOME	\$	(16,576)	\$	(22,687)	\$	5,644	\$	(35,396)

The accompanying notes are an integral part of these condensed consolidated financial statements.

Table of Contents

ALKERMES PLC AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

	2012	Six Months Ended September 30, (In thousands)	2011
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net income (loss)	\$	5,726	\$ (35,493)
Adjustments to reconcile net income (loss) to cash flows from operating activities:			
Depreciation and amortization		36,829	6,377
Share-based compensation expense		18,609	12,712
Deferred income taxes		(944)	(9,664)
Excess tax benefit from share-based compensation		(387)	(3,127)
Loss on debt refinancing transaction		12,129	
Prepayment penalty in connection with debt refinancing		(2,800)	
Principal payments on long-term debt attributable to original issue discount		(2,657)	
Other non-cash charges		4,385	719
Changes in assets and liabilities, excluding the effect of acquisitions:			
Receivables		(5,617)	733
Inventory, prepaid expenses and other assets		(3,111)	(11,921)
Accounts payable and accrued expenses		(17,422)	23,921
Deferred revenue		(2,060)	189
Other long-term liabilities		2,368	
Cash flows provided by (used in) operating activities		45,048	(15,554)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of property, plant and equipment		(11,206)	(3,654)
Sales of property, plant and equipment		17	3
Acquisition of Elan Drug Technologies, net of cash acquired			(494,962)
Purchases of investments		(99,218)	(134,801)
Sales and maturities of investments		185,392	240,363
Cash flows provided by (used in) investing activities		74,985	(393,051)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from the issuance of ordinary shares under share-based compensation arrangements		9,731	15,326
Excess tax benefit from share-based compensation		387	3,127
Proceeds from the issuance of long-term debt		368,557	444,100
Employee taxes paid related to net share settlement of equity awards		(3,323)	(3,105)
Principal payments of long-term debt		(446,568)	
Cash flows (used in) provided by financing activities		(71,216)	459,448
NET INCREASE IN CASH AND CASH EQUIVALENTS		48,817	50,843
CASH AND CASH EQUIVALENTS Beginning of period		83,601	38,394
CASH AND CASH EQUIVALENTS End of period	\$	132,418	\$ 89,237
SUPPLEMENTAL CASH FLOW DISCLOSURE:			
Cash paid for interest	\$	19,268	\$ 5,877
Cash paid for taxes	\$	2,177	\$ 15
Non-cash investing and financing activities:			
Purchased capital expenditures included in accounts payable and accrued expenses	\$	834	\$ 131

The accompanying notes are an integral part of these condensed consolidated financial statements.

Table of Contents

ALKERMES PLC AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED STATEMENTS (Unaudited)

1. THE COMPANY

Alkermes plc (the "Company") is a fully integrated, global biopharmaceutical company that applies its scientific expertise and proprietary technologies to develop innovative medicines that improve patient outcomes. The Company has a diversified portfolio of more than 20 commercial drug products and a substantial clinical pipeline of product candidates that address central nervous system ("CNS") disorders such as addiction, schizophrenia and depression. Headquartered in Dublin, Ireland, Alkermes plc has a research and development ("R&D") center in Waltham, Massachusetts; R&D and manufacturing facilities in Athlone, Ireland; and manufacturing facilities in Gainesville, Georgia and Wilmington, Ohio.

On September 16, 2011, the business of Alkermes, Inc. and the drug technologies business ("EDT") of Elan Corporation, plc ("Elan") were combined under the Company (this combination is referred to as the "Business Combination", the "acquisition of EDT" or the "EDT acquisition") in a transaction accounted for as a reverse acquisition with Alkermes, Inc. treated as the accounting acquirer. As a result, the historical financial statements of Alkermes, Inc. are included in the comparative periods. Use of the terms such as "us", "we", "our", "Alkermes" or the "Company" is meant to refer to Alkermes plc and its consolidated subsidiaries, except where the context makes clear that the time period being referenced is prior to September 16, 2011, in which case such terms shall refer to Alkermes, Inc. and its consolidated subsidiaries. Prior to September 16, 2011, Alkermes, Inc. was an independent pharmaceutical company incorporated in the Commonwealth of Pennsylvania and traded on the NASDAQ Global Select Stock Market under the symbol "ALKS".

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying condensed consolidated financial statements of the Company for the three and six months ended September 30, 2012 and 2011 are unaudited and have been prepared on a basis substantially consistent with the audited financial statements for the year ended March 31, 2012. The year-end condensed consolidated balance sheet data was derived from audited financial statements, but does not include all disclosures required by accounting principles generally accepted in the United States of America ("U.S.") (commonly referred to as "GAAP"). In the opinion of management, the condensed consolidated financial statements include all adjustments, which are of a normal recurring nature, that are necessary to present fairly the results of operations for the reported periods.

These financial statements should be read in conjunction with the financial statements and notes thereto of Alkermes, which are contained in the Company's Annual Report on Form 10-K for the year ended March 31, 2012, which has been filed with the U.S. Securities and Exchange Commission ("SEC"). The results of the Company's operations for any interim period are not necessarily indicative of the results of the Company's operations for any other interim period or for a full fiscal year.

Principles of Consolidation

The condensed consolidated financial statements include the accounts of Alkermes plc and its wholly-owned subsidiaries: Alkermes Ireland Holdings Limited, Alkermes Pharma Ireland Limited, Alkermes U.S. Holdings, Inc., Alkermes, Inc., Eagle Holdings USA, Inc., Alkermes Gainesville LLC, Alkermes Controlled Therapeutics, Inc., Alkermes Europe, Ltd., Alkermes Finance Ireland Limited, Alkermes Finance S.A R.L., Alkermes Finance Ireland (No. 2) Limited and Alkermes Science One Limited. Intercompany accounts and transactions have been eliminated.

Table of Contents

ALKERMES PLC AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED STATEMENTS (Continued)

Use of Estimates

The preparation of the Company's condensed consolidated financial statements in accordance with GAAP requires management to make estimates, judgments and assumptions that may affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, the Company evaluates its estimates and judgments and methodologies, including those related to revenue recognition and related allowances, its collaborative relationships, clinical trial expenses, the valuation of inventory, impairment and amortization of intangibles and long-lived assets, share-based compensation, income taxes including the valuation allowance for deferred tax assets, valuation of investments and derivative instruments, litigation and restructuring charges. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates under different assumptions or conditions.

Revenue Recognition

During the three months ended September 30, 2012, the Company changed the way in which revenue is recognized on VIVITROL® product sales. Prior to August 1, 2012, the Company did not have sufficient history to reasonably estimate returns related to VIVITROL shipments and therefore, the Company deferred the recognition of revenue on shipments of VIVITROL until the product left the distribution channel. During the three months ended September 30, 2012, it was determined there was sufficient history to reliably estimate returns, and revenue on the sales of VIVITROL is now recognized upon delivery to customers, which is the point in time the customer assumes the risks and rewards of ownership. This change in the method of revenue recognition resulted in a one-time \$1.7 million increase to Product sales, net, which was recognized during the three months ended September 30, 2012.

Based on this revised revenue recognition policy, a reserve is now estimated for future product returns on VIVITROL gross product sales. This estimate is based on historical return rates as well as specifically identified anticipated returns due to known business conditions and product expiry dates. Return amounts are recorded as a deduction to arrive at VIVITROL product sales, net. Once VIVITROL is returned, it is destroyed. At September 30, 2012, the product return reserve is estimated to be 2% of product sales.

Segment Information

The Company operates as one business segment, which is the business of developing, manufacturing and commercializing medicines designed to yield better therapeutic outcomes and improve the lives of patients with serious diseases. The Company's chief decision maker, the Chairman and Chief Executive Officer, reviews the Company's operating results on an aggregate basis and manages the Company's operations as a single operating unit.

Reclassifications

An amount equal to \$3.1 million that was previously classified as "Proceeds from the issuance of ordinary shares under share-based compensation arrangements" has been reclassified to "Employee taxes paid related to net share settlement of equity awards" in the accompanying condensed consolidated statements of cash flows to conform to current period presentation.

New Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") or other standard-setting bodies that are adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on its financial position or results of operations upon adoption.

In June 2011, the FASB issued guidance related to the presentation of comprehensive income. This accounting standard: (1) eliminates the option to present the components of other comprehensive income as part of the statement of changes in stockholders' equity; (2) requires the consecutive presentation of the statement of net income and other comprehensive income; and (3) requires an entity to present reclassification adjustments on the face of the financial statements from other comprehensive income to net income. The amendments in this accounting standard do not change the items that must be reported in other comprehensive income or when an item of other comprehensive income must be reclassified to net income, nor do the amendments affect how earnings per share is calculated or presented. This standard is required to be applied retrospectively and is effective for fiscal years and interim periods within those years beginning after December 15, 2011. As this accounting standard only requires enhanced disclosure, the adoption of this standard did not impact the Company's financial position or results of operations.

Table of Contents

ALKERMES PLC AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED STATEMENTS (Continued)

3. ACQUISITIONS

On September 16, 2011, the Company acquired EDT from Elan in a transaction accounted for under the acquisition method of accounting for business combinations, in exchange for \$500.0 million in cash and 31.9 million ordinary shares of Alkermes Inc., valued at \$525.1 million based on a stock price of \$16.46 per share on the acquisition date. EDT developed and manufactured pharmaceutical products that deliver clinical benefits to patients using EDT's experience and proprietary drug technologies, including the oral controlled release platform (OCR) and the bioavailability enhancement platform, including EDT's NanoCrystal® technology. The Company acquired EDT to diversify its commercialized product portfolio and pipeline candidates, enhance its financial resources in order to invest in its proprietary drug candidates, pursue additional growth opportunities and reduce its cost of capital.

The purchase price allocation resulted in the following amounts being allocated to the assets acquired and liabilities assumed at the acquisition date based upon their respective fair values summarized below (in thousands):

Cash	\$	5,225
Receivables		59,398
Inventory		29,669
Prepaid expenses and other current assets		1,806
Property plant and equipment		210,558
Acquired identifiable intangible assets		689,000
Goodwill		92,740
Other assets		4,360
Accounts payable and accrued expenses		(18,650)
Deferred tax liabilities		(48,448)
Other long-term liabilities		(584)
Total	\$	1,025,074

The following unaudited pro forma information presents the combined results of operations for the three and six months ended September 30, 2011 as if the acquisition of EDT had been completed on April 1, 2011. The unaudited pro forma results do not reflect any material adjustments, operating efficiencies or potential cost savings which may result from the consolidation of operations but do reflect certain adjustments expected to have a continuing impact on the combined results.

(In thousands, except per share data)	Three Months Ended September 30, 2011	Six Months Ended September 30, 2011
Revenues	\$ 121,090	\$ 244,049
Net loss	\$ (4,881)	\$ (7,817)
Basic and diluted loss per common share	\$ (0.04)	\$ (0.06)

Table of Contents

ALKERMES PLC AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED STATEMENTS (Continued)

4. INVESTMENTS

Investments consist of the following:

	Amortized Cost	Gains	Gross Unrealized Losses		Estimated Fair Value
			Less than One Year (In thousands)	Greater than One Year	
September 30, 2012					
Short-term investments:					
Available-for-sale securities:					
U.S. government and agency debt securities	\$ 39,494	\$ 5	\$ (3)	\$	\$ 39,496
Corporate debt securities	15,059	54			15,113
International government agency debt securities	11,217	6			11,223
	65,770	65	(3)		65,832
Money market funds	1,201				1,201
Total short-term investments	66,971	65	(3)		67,033
Long-term investments:					
Available-for-sale securities:					
Corporate debt securities	8,008			(482)	7,526
Held-to-maturity securities:					
Certificates of deposit	1,200				1,200
Total long-term investments	9,208			(482)	8,726
Total investments	\$ 76,179	\$ 65	\$ (3)	\$ (482)	\$ 75,759
March 31, 2012					
Short-term investments:					
Available-for-sale securities:					
U.S. government and agency debt securities	\$ 62,925	\$ 67	\$ (17)	\$	\$ 62,975
International government agency debt securities	25,646	22	(2)		25,666
Corporate debt securities	12,324	27			12,351
	100,895	116	(19)		100,992
Held-to-maturity securities:					
Certificates of deposit	4,236				4,236
U.S. government obligations	417				417
	4,653				4,653
Money market funds	1,201				1,201
Total short-term investments	106,749	116	(19)		106,846
Long-term investments:					
Available-for-sale securities:					
U.S. government and agency debt securities	35,493		(70)		35,423
International government agency debt securities	10,257		(20)		10,237
Corporate debt securities	8,009			(660)	7,349
Strategic investments	644	838			1,482
	54,403	838	(90)	(660)	54,491

Edgar Filing: Alkermes plc. - Form 10-Q

Held-to-maturity securities:

Certificates of deposit	1,200					1,200
Total long-term investments	55,603	838	(90)	(660)		55,691
Total investments	\$ 162,352	\$ 954	\$ (109)	\$ (660)	\$	162,537

The Company's strategic investments at March 31, 2012 include common stock in a public company with which the Company had a collaborative arrangement. The Company sold this investment during the three months ended September 30, 2012 and recorded a gain of \$1.2 million within Other income, net in the accompanying condensed consolidated statements of operations and comprehensive (loss) income.

Table of Contents

ALKERMES PLC AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED STATEMENTS (Continued)

The proceeds from the sales and maturities of marketable securities, excluding strategic equity investments, which were primarily reinvested and resulted in realized gains and losses, were as follows:

(In thousands)	Six Months Ended September 30,	
	2012	2011
Proceeds from the sales and maturities of marketable securities	\$ 185,392	\$ 240,363
Realized gains	\$ 273	\$ 37
Realized losses	\$	\$ 11

The Company's available-for-sale and held-to-maturity securities at September 30, 2012 had contractual maturities in the following periods:

(In thousands)	Available-for-sale		Held-to-maturity	
	Amortized Cost	Estimated Fair Value	Amortized Cost	Estimated Fair Value
Within 1 year	\$ 29,294	\$ 29,294	\$ 1,200	\$ 1,200
After 1 year through 5 years	44,484	44,064		
Total	\$ 73,778	\$ 73,358	\$ 1,200	\$ 1,200

At September 30, 2012, the Company believed that the unrealized losses on its available-for-sale investments were temporary. The investments with unrealized losses consisted primarily of corporate debt securities. In making the determination that the decline in fair value of these securities was temporary, the Company considered various factors, including but not limited to: the length of time each security was in an unrealized loss position; the extent to which fair value was less than cost; financial condition and near-term prospects of the issuers; and the Company's intent not to sell these securities and the assessment that it is more likely than not that the Company would not be required to sell these securities before the recovery of their amortized cost basis.

The Company's investment in Acceleron Pharma, Inc. ("Acceleron") was \$8.7 million at September 30, 2012 and March 31, 2012, which was recorded within "Other assets" in the accompanying condensed consolidated balance sheets. The Company accounts for its investment in Acceleron under the cost method as Acceleron is a privately-held company over which the Company does not exercise significant influence. The Company will continue to monitor this investment to evaluate whether any decline in its value has occurred that would be other-than-temporary, based on the implied value from any recent rounds of financing completed by Acceleron, market prices of comparable public companies and general market conditions.

The Company's investment in Civitas Therapeutics, Inc. ("Civitas") was \$1.4 million and \$2.0 million at September 30, 2012 and March 31, 2012, respectively, which was recorded within "Other assets" in the accompanying condensed consolidated balance sheets. The Company accounts for its investment in Civitas under the equity method as the Company has an approximately 11% ownership position in Civitas, has a seat on the board of directors and believes it may be able to exercise significant influence over the operating and financial policies of Civitas. During the six months ended September 30, 2012 and 2011, the Company recorded a reduction in its investment in Civitas of \$0.6 million and \$0.4 million,

respectively, which represented the Company's proportionate share of Civitas' net losses for these periods.

[Table of Contents](#)

ALKERMES PLC AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED STATEMENTS (Continued)

5. FAIR VALUE MEASUREMENTS

The following table presents information about the Company's assets and liabilities that are measured at fair value on a recurring basis and indicates the fair value hierarchy of the valuation techniques the Company utilized to determine such fair value:

(In thousands)	September 30, 2012	Level 1	Level 2	Level 3
Assets:				
Cash equivalents	\$ 1,201	\$ 1,201	\$	
U.S. government and agency debt securities	39,496	39,496		
Corporate debt securities	22,639	2,035	18,867	1,737
International government agency debt securities	11,223	3,122	8,101	
Total	\$ 74,559	\$ 45,854	\$ 26,968	\$ 1,737
Liabilities:				
Interest rate swap contract	\$ (626)	\$	\$ (626)	\$
Total	\$ (626)	\$	\$ (626)	\$

(In thousands)	March 31, 2012	Level 1	Level 2	Level 3
Assets:				
Cash equivalents	\$ 1,201	\$ 1,201	\$	
U.S. government and agency debt securities	98,398	98,398		
International government agency debt securities	35,903	30,902		5,001
Corporate debt securities	19,700		14,045	5,655
Strategic equity investments	1,482	1,482		
Interest rate cap contracts	20		20	
Total	\$ 156,704	\$ 131,983	\$ 14,065	\$ 10,656
Liabilities:				
Interest rate swap contract	\$ (522)	\$	\$ (522)	\$
Total	\$ (522)	\$	\$ (522)	\$

The Company transfers its financial assets and liabilities measured at fair value on a recurring basis between the fair value hierarchies at the end of each reporting period. The following table illustrates the rollforward of the fair value of the Company's investments whose fair value was determined using Level 3 inputs:

(In thousands)	Fair Value
Balance, April 1, 2012	\$ 10,656
Investments transferred into Level 3	1,579

Edgar Filing: Alkermes plc. - Form 10-Q

Investments transferred out of Level 3		(10,510)
Total unrealized gains included in comprehensive loss		12
Balance, September 30, 2012	\$	1,737

Table of Contents

ALKERMES PLC AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED STATEMENTS (Continued)

During the six months ended September 30, 2012, there was one investment in corporate debt securities transferred from Level 2 to Level 1 as trading in this security increased to a level such that the fair value for the security could be derived from a quoted price in an active market. There were no transfers of any securities from Level 1 to Level 2 during the six months ended September 30, 2012.

During the six months ended September 30, 2012, there was one investment in corporate debt securities and one investment in international government agency debt securities that were transferred from Level 3 to Level 2 as trading in these securities resumed during the period. Also, during the six months ended September 30, 2012, there were two investments in corporate debt securities that were transferred from Level 2 to Level 3 as trading in these securities ceased during the period.

The Company's international government agency debt securities and corporate debt securities classified as Level 2 were initially valued at the transaction price and subsequently valued, at the end of each reporting period, utilizing market observable data. The market observable data includes reportable trades, benchmark yields, credit spreads, broker/dealer quotes, bids, offers, current spot rates and other industry and economic events. The Company validates the prices developed using the market observable data by obtaining market values from other pricing sources, analyzing pricing data in certain instances and confirming that the relevant markets are active.

The Company's Level 3 securities consisted of two corporate debt securities that were not currently trading, and a third-party pricing service was used to determine the estimated fair value of these securities. The third-party pricing service develops its estimate of fair value through a proprietary model using variables including reportable trades and last trade date, bids and offers, trading frequency, benchmark yields, credit spreads and other industry and economic events. The Company validates the prices provided by its third-party pricing service by reviewing their pricing methods and matrices, obtaining market values from other pricing sources, analyzing pricing data in certain instances and confirming the activity in the relevant markets. After completing its validation procedures, the Company did not adjust or override any fair value measurements provided by its pricing services at September 30, 2012.

In September and December 2011, the Company entered into interest rate cap agreements, and, in September 2011, the Company entered into an interest rate swap agreement. These agreements are described in greater detail in Note 11, *Derivative Instruments*. The fair value of the Company's interest rate cap and interest rate swap agreements were based on an income approach, which excludes accrued interest, and takes into consideration then-current interest rates and then-current creditworthiness of the Company or the counterparty, as applicable.

The carrying amounts reflected in the condensed consolidated balance sheets for cash and cash equivalents, accounts receivable, other current assets, accounts payable and accrued expenses approximate fair value due to their short-term nature. The fair value of the remaining financial instruments not currently recognized at fair value on the Company's condensed consolidated balance sheets consist of the \$300.0 million, seven-year term loan bearing interest at three-Month LIBOR plus 3.5% (Term Loan B-1) and the \$75.0 million, four-year term loan bearing interest at three-Month LIBOR plus 3.0% (Term Loan B-2) and together with Term Loan B-1, the New Term Loan Facility. The estimated fair value of these term loans, which was based on quoted market price indications (Level 2 in the fair value hierarchy), and may not be representative of actual values that could have been or will be realized in the future at September 30, 2012, was as follows:

Edgar Filing: Alkermes plc. - Form 10-Q

(In thousands)	Carrying Value	Estimated Fair Value
Term Loan B-1	\$ 295,970	\$ 300,000
Term Loan B-2	\$ 74,627	\$ 75,281

6. INVENTORY

Inventory is stated at the lower of cost or market value. Cost is determined using the first-in, first-out method. Inventory consisted of the following:

(In thousands)	September 30, 2012	March 31, 2012
Raw materials	\$ 13,803	\$ 12,841
Work in process	9,450	9,569
Finished goods (1)	17,634	16,968
Consigned-out inventory (2)		381
Total inventory	\$ 40,887	\$ 39,759

Table of Contents

ALKERMES PLC AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED STATEMENTS (Continued)

(1) At September 30, 2012 and March 31, 2012, the Company had \$1.1 million and \$1.3 million, respectively, of finished goods inventory located at its third-party warehouse and shipping service provider.

(2) At March 31, 2012, consigned-out inventory related to VIVITROL inventory in the distribution channel for which the Company had not recognized revenue.

7. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment consisted of the following:

(In thousands)	September 30, 2012	March 31, 2012
Land	\$ 8,189	\$ 8,189
Building and improvements	141,147	139,820
Furniture, fixture and equipment	191,323	177,729
Leasehold improvements	24,050	45,798
Construction in progress	37,508	44,766
Subtotal	402,217	416,302
Less: accumulated depreciation	(106,843)	(113,307)
Total property, plant and equipment, net	\$ 295,374	\$ 302,995

The Company reclassified \$11.5 million of Furniture, fixture, and equipment and \$0.7 million of Land at March 31, 2012 as Buildings and improvements to revise prior period presentation.

8. GOODWILL AND INTANGIBLE ASSETS

Goodwill and intangible assets consisted of the following:

(In thousands)	Weighted Amortizable Life	Gross Carrying Amount	September 30, 2012 Accumulated Amortization	Net Carrying Amount
Goodwill		\$ 92,740	\$	\$ 92,740

Edgar Filing: Alkermes plc. - Form 10-Q

Finite-lived intangible assets:					
Collaboration agreements	12	\$	499,700	\$	(33,981) \$ 465,719
NanoCrystal technology	13		74,600		(3,610) 70,990
OCR technology	12		66,300		(6,145) 60,155
Total		\$	640,600	\$	(43,736) \$ 596,864

The Company recorded \$21.0 million of amortization expense related to its intangible assets during the six months ended September 30, 2012. Based upon the Company's most recent analysis, the Company expects the amortization of intangible assets included within its condensed consolidated balance sheet as of September 30, 2012 to be in the range of approximately \$42.0 million to \$70.0 million annually over the next five fiscal years.

Table of Contents

ALKERMES PLC AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED STATEMENTS (Continued)

9. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consisted of the following:

(In thousands)	September 30, 2012	March 31, 2012
Accounts payable	\$ 15,588	\$ 18,400
Accrued compensation	13,992	25,023
Accrued interest	275	2,472
Accrued other	28,551	33,259
Total accounts payable and accrued expenses	\$ 58,406	\$ 79,154

10. LONG-TERM DEBT

Long-term debt consisted of the following:

(In thousands)	September 30, 2012	March 31, 2012
Term Loan B-1, due September 25, 2019	\$ 295,970	\$
Term Loan B-2, due September 25, 2016	74,627	
First Lien Term Loan, due September 16, 2017		306,822
Second Lien Term Loan, due September 16, 2018		137,638
Total	370,597	444,460
Less: current portion	(6,750)	(3,100)
Long-term debt	\$ 363,847	\$ 441,360

In September 2012, the Company entered into the New Term Loan Facility to refinance its \$310.0 million first lien term loan facility (the First Lien Term Loan) and \$140.0 million second lien term loan facility (the Second Lien Term Loan) and, together with the First Lien Term Loan, the Term Loans). The First Lien Term Loan was amended and restated to, among other things, provide for new term loans under the New Term Loan Facility, including Term Loan B-1 and Term Loan B-2, the proceeds of which, together with cash on hand, were used to repay the balance of the Term Loans (the Debt Refinancing). Term Loan B-1 has a principal balance of \$300.0 million, matures on September 25, 2019, bears interest at three-month LIBOR plus 3.5% and was issued with an original issue discount of \$3.0 million. Term Loan B-2 has a principal balance of \$75.0 million, matures on September 25, 2016, bears interest at three-month LIBOR plus 3.0% and was issued with an original issue discount of \$0.4 million. Under the New Term Loan Facility, LIBOR for both tranches is subject to an interest rate floor of 1.0%. Term Loan B-1 amortizes in equal quarterly amounts of 0.25% of the original principal amount of the loan, with the balance payable at maturity. Term Loan B-2 amortizes in equal quarterly amounts of 1.25% of the original principal amount of the loan for the first three years after funding, with the balance payable at maturity. The New Term Loan Facility is guaranteed by certain subsidiaries of the Company (the Guarantors) and is secured by a first priority lien on substantially all of the assets and properties of the Company and the Guarantors (subject to certain exceptions and limitations).

Edgar Filing: Alkermes plc. - Form 10-Q

Scheduled maturity with respect to the New Term Loan Facility is as follows (in thousands):

Fiscal Year:

2013	\$	3,375
2014		6,750
2015		6,750
2016		6,750
2017		64,875
Thereafter		286,500
Total	\$	375,000

Table of Contents

ALKERMES PLC AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED STATEMENTS (Continued)

Required quarterly principal payments of \$0.8 million on Term Loan B-1 and \$0.9 million on Term Loan B-2 begin on December 31, 2012. Commencing with the completion of the Company's fiscal year ended March 31, 2014, the Company is subject to mandatory prepayments of principal if certain excess cash flow thresholds, as defined in the New Term Loan Facility, are met. The Company may make prepayments of principal without premium or penalty, however, in the event that, prior to September 25, 2013, the Company prepays any of Term Loan B-1 or Term Loan B-2 pursuant to repricing transaction or an amendment of the New Term Loan Facility that results in a repricing transaction, the Company will be subject to a prepayment premium of 1% of the amount of the term loan being repaid or the aggregate amount of the applicable term loan outstanding immediately prior to such amendment.

The New Term Loan Facility has incremental facility capacity in an amount of \$140.0 million, plus additional amounts as long as the Company meets certain conditions, including a specified leverage ratio. The New Term Loan Facility includes a number of restrictive covenants that, among other things and subject to certain exceptions and baskets, impose operating and financial restrictions on the Company and certain of its subsidiaries. The New Term Loan Facility also contains customary affirmative covenants and events of default. The Company was in compliance with its debt covenants at September 30, 2012.

The Debt Refinancing was a restructuring of the Term Loans and involved multiple lenders who were considered members of a loan syndicate. In determining whether the Debt Refinancing was to be accounted for as a debt extinguishment or modification, the Company considered whether creditors remained the same or changed and whether the change in debt terms was substantial. The terms of the New Term Loan Facility were considered substantially different from the original Term Loans if the present value of the cash flows under the New Term Loan Facility was at least 10% different from the present value of the remaining cash flows under the Term Loans (commonly referred to as the 10% Test). The Company performed a separate 10% Test for each individual creditor participating in the loan syndication. The loans of creditors who did not participate in the New Term Loan Facility were accounted for as a debt extinguishment.

As the New Term Loan Facility has a prepayment option exercisable at any time, the Company assumed the prepayment option was exercised immediately on the date of the refinancing for purposes of applying the 10% Test. When there was a change in principal balance for individual creditors in the Debt Refinancing, in applying the 10% Test, the Company used the cash flows related to the lowest common principal balance between the Term Loans and the New Term Loan Facility (commonly referred to as the Net Method). Under the Net Method, any principal in excess of a creditor's rollover money was treated as a new, separate debt issuance, and any decrease in principal was treated as a partial extinguishment of debt.

New costs paid to creditors and third parties in connection with the Debt Refinancing were allocated to the New Term Loan Facility and then further allocated to each creditor. Once these costs were allocated to the individual creditors, an analysis of each creditor was performed and a determination made as to whether the refinancing was accounted for as a debt extinguishment or modification under the 10% Test. For debt considered to be extinguished, the unamortized deferred financing costs and unamortized original issue discount associated with the extinguished debt were expensed. For debt considered to be modified, the unamortized deferred financing costs and unamortized original issue discount associated with the modified debt continue to be amortized, new financing costs were expensed and new third-party fees were capitalized. For new creditors in the Debt Refinancing, new financing costs and original issue discount fees were capitalized and will be amortized over the estimated repayment period of the new debt.

Edgar Filing: Alkermes plc. - Form 10-Q

The Debt Refinancing resulted in a \$12.1 million charge in the three months ended September 30, 2012, which was included in Interest expense in the accompanying condensed consolidated statement of operations and comprehensive (loss) income and was comprised of the following (in thousands):

Extinguished debt:		
Unamortized deferred financing costs	\$	4,600
Unamortized original issue discount		2,657
Modified debt:		
Debt financing costs		1,967
Original issue discount		105
Prepayment penalty		2,800
Total	\$	12,129

Table of Contents

ALKERMES PLC AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED STATEMENTS (Continued)

At September 30, 2012, the Company's balance of unamortized deferred financing costs and unamortized original issue discount costs were \$4.6 million and \$4.4 million, respectively. These costs are being amortized to interest expense over the estimated repayment period of the new debt using the effective interest method. During the six months ended September 30, 2012, and 2011, the Company had amortization expense of \$3.0 million and \$0.3 million, respectively, related to deferred financing costs and original issue discount.

11. DERIVATIVE INSTRUMENTS

In December 2011, the Company entered into an interest rate cap agreement with Morgan Stanley Capital Services LLC (MSCS) at a cost of \$0.1 million to mitigate the impact of fluctuations in the three-month LIBOR rate at which the Company's long-term debt bear interest. The interest rate cap agreement expires in December 2013, has a notional value of \$160.0 million and is not designated as a hedging instrument. The Company recorded an immaterial amount of loss as Other income, net in the accompanying condensed consolidated statements of operations and comprehensive (loss) income due to the increase in value of this contract during the six months ended September 30, 2012. At September 30, 2012, this contract has an immaterial balance included within Other assets in the accompanying condensed consolidated balance sheet.

In September 2011, the Company entered into an interest rate cap agreement with HSBC Bank USA at a cost of less than \$0.1 million to mitigate the impact of fluctuations in the three-month LIBOR rate at which the Company's long-term debt bear interest. The interest rate cap agreement became effective on September 16, 2011, expires in December 2012, has a notional value of \$65.0 million and is not designated as a hedging instrument. The Company recorded an immaterial amount of loss within Other income, net in the accompanying condensed consolidated statements of operations and comprehensive (loss) income due to the decline in value of this contract during the six months ended September 30, 2012. At September 30, 2012, this contract has no value.

In September 2011, the Company entered into an interest rate swap agreement with MSCS to mitigate the impact of fluctuations in the three-month LIBOR rate at which the Company's long-term debt bear interest. The interest rate swap agreement becomes effective in December 2012, expires in December 2014 and has a notional value of \$65.0 million. This contract was designated as a cash flow hedge, however, in connection with the Debt Refinancing, the cash flow hedge was deemed to no longer be effective for accounting purposes and accordingly, the Company reclassified its unrealized losses of \$0.6 million to Interest expense in the accompanying condensed consolidated statement of operations and comprehensive (loss) income. At September 30, 2012, the interest rate swap was no longer designated as a cash flow hedge. The following table summarizes the beginning and ending accumulated derivative loss for the interest rate swap:

Unrealized losses included in accumulated other comprehensive income at March 31, 2012	\$	(522)
Unrealized losses incurred during the six months ended September 30, 2012		(72)
Reclassification of unrealized losses to realized losses during the six months ended September 30, 2012		594
Unrealized losses included in accumulated other comprehensive income at September 30, 2012	\$	

The following table summarizes the fair value and presentation in the condensed consolidated balance sheets for derivatives not designated and designated as hedging instruments:

Edgar Filing: Alkermes plc. - Form 10-Q

(In thousands)	Balance Sheet Location	Fair Value	
		September 30, 2012	March 31, 2012
<i>Interest rate swap</i>			
Liability derivative not designated as a cash flow hedge	Other long-term liabilities	\$ (626)	
Liability derivative designated as a cash flow hedge	Other long-term liabilities	\$	(522)

Table of Contents

ALKERMES PLC AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED STATEMENTS (Continued)

12. SHARE-BASED COMPENSATION

Share-based compensation expense consisted of the following:

(In thousands)	Three Months Ended September 30,		Six Months Ended September 30,	
	2012	2011	2012	2011
Cost of goods manufactured and sold	\$ 1,223	\$ 529	\$ 2,304	\$ 1,085
Research and development	2,348	2,309	4,658	4,244
Selling, general and administrative	6,876	4,214	11,647	7,383
Total share-based compensation expense	\$ 10,447	\$ 7,052	\$ 18,609	\$ 12,712

At September 30, 2012 and March 31, 2012, \$0.5 million and \$0.4 million, respectively, of share-based compensation cost was capitalized and recorded as Inventory in the condensed consolidated balance sheets.

13. (LOSS) EARNINGS PER SHARE

Basic (loss) earnings per ordinary share is calculated based upon net (loss) income available to holders of ordinary shares divided by the weighted average number of shares outstanding. For the calculation of diluted (loss) earnings per ordinary share, the Company uses the weighted average number of ordinary shares outstanding, as adjusted for the effect of potential outstanding shares, including stock options and restricted stock units.

(In thousands)	Three Months Ended September 30,		Six Months Ended September 30,	
	2012	2011	2012	2011
Numerator:				
Net (loss) income	\$ (16,707)	\$ (22,255)	\$ 5,726	\$ (35,493)
Denominator:				
Weighted average number of ordinary shares outstanding	131,067	102,474	130,753	99,578
Effect of dilutive securities:				
Stock options			3,604	
Restricted stock units			1,232	
Dilutive ordinary share equivalents			4,836	
Shares used in calculating diluted (loss) earnings per share	131,067	102,474	135,589	99,578

Edgar Filing: Alkermes plc. - Form 10-Q

The following potential ordinary equivalent shares have not been included in the net (loss) income per ordinary share calculations because the effect would have been anti-dilutive.

(In thousands)	Three Months Ended September 30,		Six Months Ended September 30,	
	2012	2011	2012	2011
Stock options	9,986	8,084	6,472	8,076
Restricted stock units	1,238	1,457		1,555
Total	11,224	9,541	6,472	9,631

Table of Contents

ALKERMES PLC AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED STATEMENTS (Continued)

14. INCOME TAXES

The Company recorded an income tax provision of \$0.4 million and \$1.2 million for the three and six months ended September 30, 2012, respectively, and an income tax provision of \$3.7 million and \$3.6 million for the three and six months ended September 30, 2011, respectively. The tax provision of \$0.4 million and \$1.2 million in the three and six months ended September 30, 2012 primarily related to foreign taxes on income and was prepared on a discrete quarterly and year-to-date basis, respectively, as the yearly effective tax rate was not considered a reliable estimate for the current quarter and year-to-date provision. The income tax provision in the three and six months ended September 30, 2011 primarily related to a \$13.2 million current tax expense on the taxable transfer of the BYDUREON® intellectual property from the U.S. to Ireland and a deferred tax benefit of \$9.5 million in connection with the Business Combination, as the Company recorded a U.S. deferred tax liability in purchase accounting allowing for the partial release of an existing valuation allowance.

The Company records a deferred tax asset or liability based on the difference between the financial statement and tax basis of its assets and liabilities, as measured by enacted jurisdictional tax rates assumed to be in effect when these differences reverse. As of September 30, 2012, the Company determined, based on the weight of all available evidence, that it is not more likely than not that its remaining U.S. and Irish deferred tax assets will be realized and hence a valuation allowance was recorded on the net deferred tax asset.

15. COMMITMENTS AND CONTINGENCIES

From time to time, the Company may be subject to legal proceedings and claims in the ordinary course of business. The Company is not aware of any current proceedings or claims that it believes will have, individually or in the aggregate, a material adverse effect on its business, financial condition or results of operations.

Table of Contents

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion should be read in conjunction with our condensed consolidated financial statements and related notes beginning on page 3 of this Quarterly Report on Form 10-Q (Form 10-Q), and Management's Discussion and Analysis of Financial Condition and Results of Operations and the financial statements and notes thereto included in the Annual Report on Form 10-K for the year ended March 31, 2012 (the Annual Report), which has been filed with the Securities and Exchange Commission (SEC).

On September 16, 2011, the business of Alkermes, Inc. and the drug technologies business (EDT) of Elan Corporation, plc (Elan) were combined under Alkermes plc (this combination is referred to as the Business Combination, the acquisition of EDT or the EDT acquisition). Use of the terms such as us, we, our, Alkermes or the Company in this Form 10-Q is meant to refer to Alkermes plc and its consolidated subsidiaries except where the context makes clear that the time period being referenced is prior to September 16, 2011, in which case such terms shall refer to Alkermes, Inc. and its consolidated subsidiaries. Prior to September 16, 2011, Alkermes, Inc. was an independent pharmaceutical company incorporated in the Commonwealth of Pennsylvania and traded on the NASDAQ Global Select Stock Market (the NASDAQ) under the symbol ALKS.

Alkermes plc is a fully integrated, global biopharmaceutical company that applies its scientific expertise and proprietary technologies to develop innovative medicines that improve patient outcomes. We have a diversified portfolio of more than 20 commercial drug products and a clinical pipeline of product candidates that address central nervous system (CNS) disorders such as addiction, schizophrenia and depression. Headquartered in Dublin, Ireland, we have a research and development (R&D) center in Waltham, Massachusetts; R&D and manufacturing facilities in Athlone, Ireland; and manufacturing facilities in Gainesville, Georgia and Wilmington, Ohio.

We leverage our formulation expertise and proprietary product platforms to develop, both with partners and on our own, innovative and competitively advantaged medications that can enhance patient outcomes in major therapeutic areas. We enter into select collaborations with pharmaceutical and biotechnology companies to develop significant new product candidates, based on existing drugs and incorporating our proprietary product platforms. In addition, we apply our innovative formulation expertise and drug development capabilities to create our own new, proprietary pharmaceutical products.

Forward-Looking Statements

This document contains and incorporates by reference forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. In some cases, these statements can be identified by the use of forward-looking terminology such as may, will, could, should, would, expect, anticipate, continue or other similar words. These statements discuss future expectations, contain projections of results of operations or of financial condition, or state trends and known uncertainties or other forward looking information. Forward-looking statements in this Form 10-Q include, without limitation, statements regarding:

- our expectations regarding our financial performance, including revenues, expenses, gross margins, liquidity, capital expenditures and income taxes;

Edgar Filing: Alkermes plc. - Form 10-Q

- our expectations regarding the commercialization of our products;
- our expectations regarding our products, including the development, regulatory review (including expectations about regulatory approval and regulatory timelines) and therapeutic and commercial potential of such products and the costs and expenses related thereto;
- our expectations regarding the initiation, timing and results of clinical trials of our products;
- our expectations regarding the competitive landscape, and changes therein, related to our products;
- our expectations regarding our collaborations and other significant agreements relating to our products;
- our expectations regarding the impact of new accounting pronouncements;
- our expectations regarding our intellectual property rights, ability to protect our intellectual property rights and not infringe upon third-party intellectual property rights;
- our expectations regarding near-term changes in the nature of our market risk exposures or in management's objectives and strategies with

Table of Contents

respect to managing such exposures; and

- our expectations regarding future capital requirements and capital expenditures and our ability to finance our operations and capital requirements.

You are cautioned that forward-looking statements are based on current expectations and are inherently uncertain. Actual performance and results of operations may differ materially from those projected or suggested in the forward-looking statements due to various risks and uncertainties, including the risks and uncertainties described or discussed in this Form 10-Q and in our Annual Report (including, without limitation, in Item 1A *Risk Factors* thereof).

The forward-looking statements contained and incorporated herein represent our judgment as of the date of this Form 10-Q, and we caution readers not to place undue reliance on such statements. The information contained in this Form 10-Q is provided by us as of the date of this Form 10-Q and, except as required by law, we do not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

Executive Summary

On September 16, 2011, in connection with the Business Combination, we paid Elan \$500.0 million in cash and issued Elan 31.9 million ordinary shares, which had a fair value of \$525.1 million on the closing date of the Merger, for the EDT business. The Business Combination was accounted for using the acquisition method of accounting for business combinations with Alkermes, Inc. being treated as the accounting acquirer under accounting principles generally accepted in the United States (U.S.) (GAAP). As a result, the operating results of Alkermes, Inc. are included for all periods being presented, whereas the operating results of the acquiree, EDT, are included only after the date of acquisition.

Net loss for the three months ended September 30, 2012, was \$16.7 million or \$0.13 per ordinary share basic and diluted, as compared to a net loss of \$22.3 million, or \$0.22 per ordinary share basic and diluted for the three months ended September 30, 2011. Net income for the six months ended September 30, 2012, was \$5.7 million or \$0.04 per ordinary share basic and diluted, as compared to a net loss of \$35.5 million, or \$0.36 per ordinary share basic and diluted for the six months ended September 30, 2011.

Total revenues increased by 72% and 106% during the three and six months ended September 30, 2012, respectively, as compared to the three and six months ended September 30, 2011, primarily due to the expansion of our product portfolio as a result of the Business Combination. Operating expenses increased by 42% and 50% during the three and six months ended September 30, 2012, respectively, as compared to the three and six months ended September 30, 2011, primarily due the inclusion of expenses associated with the former EDT business and increased clinical study costs due to the advancement of pipeline candidates into later stages of development, partially offset by the elimination of one-time merger-related costs related to the Business Combination.

In September 2012, we entered into a new term loan facility, which includes a \$300.0 million, seven-year term loan bearing interest at three-month LIBOR plus 3.5% (Term Loan B-1) and a \$75.0 million, four-year term loan bearing interest at three-month LIBOR plus 3.0%

Edgar Filing: Alkermes plc. - Form 10-Q

(Term Loan B-2 and together with Term Loan B-1, the New Term Loan Facility). The New Term Loan Facility refinanced our \$310.0 million first lien term loan facility (the First Lien Term Loan) and the \$140.0 million second lien term loan facility (the Second Lien Term Loan and, together with the First Lien Term Loan, the Term Loans) and reduced our overall outstanding debt in the process to \$375.0 million (the Debt Refinancing). Under the New Term Loan Facility, LIBOR for both tranches is subject to an interest rate floor of 1.0%. We expect that the refinancing transaction will result in savings of approximately \$18.0 million in cash interest annually. The Debt Refinancing resulted in a charge of \$12.1 million in the three months ended September 30, 2012, which was recorded within Interest expense in the accompanying condensed consolidated statement of operations and comprehensive (loss) income.

Table of Contents**COMMERCIAL PRODUCT PORTFOLIO**

Our commercial products are described in the table below, including, among other things, the territory in which the marketer has the right to sell the product and the source of revenues for us:

Product	Indication	Technology	Territory	Revenue Source	Marketer
<i>RISPERDAL</i> ® <i>CONSTA</i> ®	Schizophrenia Bipolar I Disorder	Extended-release microsphere	Worldwide	Manufacturing and Royalty	Janssen
<i>INVEGA</i> ® <i>SUSTENNA</i> ®/ <i>XEPLION</i> ®	Schizophrenia	NanoCrystal®	Worldwide	Royalty	Janssen
<i>AMPYRA</i> ® <i>FAMPYRA</i> ®	Treatment to improve walking in patients with multiple sclerosis (MS), as demonstrated by an increase in walking speed	Oral Controlled Release (OCR) (MXDAS®)	U.S. Worldwide	Manufacturing and Royalty	Acorda Therapeutics, Inc. (Acorda) in U.S. Biogen Idec (ex-U.S. under sublicense from Acorda)
<i>BYDUREON</i> ®	Type 2 diabetes	Extended-release microsphere	U.S. Worldwide	Royalty	Bristol-Myers Squibb Company (Bristol-Myers) and AstraZeneca PLC (Astra Zeneca)
<i>VIVITROL</i> ®	Alcohol dependence Opioid dependence	Extended-release microsphere	U.S. Russia and Commonwealth of Independent States (CIS)	Product sales Manufacturing and Royalty	Alkermes plc; Cilag GmbH International (Cilag)
<i>TRICOR</i> ®/ <i>LIPANTHYL</i> ®/ <i>LIPIDIL</i> ®/ <i>SUPRALIP</i> ®	Cholesterol lowering	NanoCrystal	Worldwide	Royalty	Abbott
<i>ZANAFLEX</i> ® <i>CAPSULES</i> ®/ <i>ZANAFLEX</i> ® <i>TABLETS</i>	Muscle spasticity	OCR (SODAS®)	U.S.	Manufacturing and Royalty	Acorda
<i>AVINZA</i> ®	Chronic moderate to severe pain	OCR (SODAS)	U.S.	Manufacturing and Royalty	Pfizer
<i>EMEND</i> ®	Nausea associated with chemotherapy and surgery	NanoCrystal	Worldwide	Manufacturing and Royalty	Merck
<i>FOCALIN</i> ® XR/ <i>RITALIN LA</i> ®	Attention Deficit Hyperactivity Disorder	OCR (SODAS)	Worldwide	Manufacturing and Royalty	Novartis
<i>MEGACE</i> ® ES	Cachexia associated with AIDS	NanoCrystal	U.S.	Royalty	Strativa Pharmaceuticals (a business division of Par Pharmaceutical Companies, Inc.)
<i>LUVOX CR</i> ®	Obsessive-compulsive disorder	OCR (SODAS)	U.S.	Manufacturing and Royalty	Jazz Pharmaceuticals plc
<i>RAPAMUNE</i> ®		NanoCrystal	Worldwide	Manufacturing	Pfizer

Edgar Filing: Alkermes plc. - Form 10-Q

	Prevention of renal transplant rejection				
<i>NAPRELAN</i> ®	Various mild to moderate pain indications	OCR (IPDAS®)	U.S. Canada	Manufacturing	Shionogi; Sunovion Pharmaceuticals Canada, Inc.

Table of Contents

<i>VERELAN®/ VERELAN® PM/ VERAPAMIL PM/ VERAPAMIL SR/ UNIVER® VERECAPS®/</i>	Hypertension	OCR (SODAS)	Licensed on country/region basis throughout the world	Manufacturing	UCB Kremers-Urban Watson; Cephalon; Aspen; Orient Europharma
<i>DILZEM SR/ DILZEM XL/ DILTELAN/ ACALIX CD/ DINISOR/ TILAZEM CR/ CARDIZEM CD</i>	Hypertension and/or Angina	OCR (SODAS)	Licensed on country/region basis throughout the world	Manufacturing and Royalty (for CARDIZEM CD only)	Cephalon; Pfizer; Roemmers; Kun Wha; Orient Europharma; Sanofi-Aventis
<i>AFEDitab® CR (AB Rated to Adalat CC®) (Nifedipine)</i>	Hypertension	OCR (MXDAS®)	U.S.	Manufacturing	Watson Pharmaceutical

KEY COMMERCIAL PRODUCTS

The following five principal commercial products in our commercial product portfolio are expected to contribute meaningfully to our revenues.

RISPERDAL CONSTA and INVEGA SUSTENNA/XEPLION

RISPERDAL CONSTA and INVEGA SUSTENNA/XEPLION, which are two long-acting atypical antipsychotics, incorporate our injectable extended-release microsphere and NanoCrystal technology, respectively. They are products of Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica International, a division of Cilag International AG (Janssen). RISPERDAL CONSTA is the first and only long-acting, atypical antipsychotic approved by the U.S. Food and Drug Administration (FDA) for the treatment of schizophrenia and for the treatment of bipolar I disorder. INVEGA SUSTENNA/XEPLION is a once-monthly, long-acting injectable atypical antipsychotic approved by the FDA for the acute and maintenance treatment of schizophrenia in adults.

AMPYRA/FAMPYRA

Dalfampridine extended-release tablets are marketed and sold in the U.S. under the trade name AMPYRA by Acorda. Prolonged-release fampridine tablets are marketed and sold outside the U.S. under the trade name FAMPYRA by Biogen Idec. AMPYRA was approved by the FDA in January 2010 as a treatment to improve walking in patients with MS as demonstrated by an increase in walking speed. Efficacy was shown in people with all four major types of MS (relapsing remitting, secondary progressive, progressive relapsing and primary progressive). It is the first and, currently, only product to be approved for this indication. The product incorporates our OCR technology. FAMPYRA is currently being sold by Biogen Idec in select countries outside of the U.S. AMPYRA and FAMPYRA are manufactured by us.

BYDUREON

We collaborated with Amylin on the development of a once-weekly formulation of exenatide, BYDUREON, for the treatment of type 2 diabetes. BYDUREON, a once-weekly formulation of exenatide, the active ingredient in Amylin's BYETTA® (exenatide), uses our polymer-based microsphere injectable extended-release technology.

On August 8, 2012, Bristol-Myers successfully completed its acquisition of Amylin. Following the acquisition, Amylin became a wholly-owned subsidiary of Bristol-Myers. On August 9, 2012, Bristol-Myers and AstraZeneca announced the expansion of their diabetes collaboration to include the co-development and marketing of Amylin's portfolio of products, including BYDUREON.

VIVITROL

VIVITROL is the first and only once-monthly injectable medication for the treatment of alcohol dependence and the prevention of relapse to opioid dependence, following opioid detoxification. The medication uses our polymer-based microsphere injectable extended-release technology to deliver and maintain therapeutic medication levels in the body through just one injection every four weeks. We developed, and

Table of Contents

currently market and sell, VIVITROL in the U.S., and Cilag sells VIVITROL in Russia and other countries in the Commonwealth of Independent States (CIS).

Other Commercial Products

We expect revenues from our other commercial products will decrease in the future due to existing and expected competition from generic manufacturers, as discussed in greater detail herein.

KEY DEVELOPMENT PROGRAMS

We also have several proprietary and partnered product candidates in various stages of development.

We are studying ALKS 9070 for the treatment of schizophrenia. ALKS 9070 is designed to provide once-monthly dosing of a medication that converts *in vivo* into aripiprazole, a molecule that is commercially available under the name ABILIFY®. ALKS 9070 is our first product candidate to leverage our proprietary LinkeRx product platform. A phase 3 trial to assess the efficacy, safety and tolerability of ALKS 9070 in approximately 690 patients experiencing acute exacerbation of schizophrenia is currently on-going, and the clinical data from this study, expected by the end of calendar-year 2013, will form the basis of a New Drug Application (NDA) to the FDA for ALKS 9070 for the treatment of schizophrenia.

ALKS 5461 is a combination of ALKS 33 and buprenorphine that we are developing to be a non-addictive therapy for the treatment of major depressive disorder (MDD) in patients who have an inadequate response to standard antidepressant therapies. ALKS 5461 has also been evaluated for the treatment of cocaine dependence. A phase 2 study is currently on-going to evaluate the efficacy and safety of ALKS 5461 when administered once daily for four weeks in approximately 130 patients with MDD who have inadequate response to standard antidepressant therapies. Data from this study are expected in the first half of calendar year 2013.

ALKS 33 is an oral opioid modulator characterized by limited hepatic metabolism and durable pharmacologic activity in modulating brain opioid receptors. ALKS 33 is being evaluated as a potential treatment for alcohol dependence; there are currently no ongoing clinical trials of ALKS 33 for the treatment of alcohol dependence.

ZOXYDRO ER (hydrocodone bitartrate extended-release capsules) is a novel, oral, single-entity (without acetaminophen), controlled-release formulation of hydrocodone in development by Zogenix, Inc. (Zogenix) for the U.S. market. ZOXYDRO ER utilizes our oral controlled-release technology, which potentially enables longer-lasting and more consistent pain relief with fewer daily doses than the commercially available formulations of hydrocodone. In May 2012, Zogenix announced that it submitted an NDA to the FDA for ZOXYDRO ER, and in July 2012, Zogenix announced that the FDA accepted for review the NDA for ZOXYDRO ER. The FDA has assigned a target action date of March 1, 2013 for the ZOXYDRO ER NDA. We have also entered into a license and distribution agreement with Paladin Labs Inc. in respect of ZOXYDRO ER in Canada. We will earn manufacturing revenues and a royalty on U.S. and Canadian sales of ZOXYDRO ER, if approved and when commercialized. We have maintained all rights to the product in territories outside the U.S. and Canada and will seek to develop and license the

product through commercial partnerships in those territories.

Results of Operations

Manufacturing and Royalty Revenues

(In millions)	Three Months Ended September 30,		Change Favorable/ (Unfavorable)	Six Months Ended September 30,		Change Favorable/ (Unfavorable)
	2012	2011		2012	2011	
Manufacturing and royalty revenues:						
RISPERDAL CONSTA	\$ 34.0	\$ 44.3	\$ (10.3)	\$ 70.8	\$ 92.8	\$ (22.0)
INVEGA SUSTENNA/XEPLION	16.3	0.6	15.7	28.1	0.6	27.5
TRICOR 145	12.5	1.8	10.7	24.5	1.8	22.7
AMPYRA/FAMPYRA	5.0	0.6	4.4	22.2	0.6	21.6
RITALIN LA/FOCALIN XR	9.1	1.5	7.6	20.0	1.5	18.5
VERELAN	5.8	1.5	4.3	11.8	1.5	10.3
Other	24.6	3.7	20.9	68.3	4.2	64.1
Manufacturing and royalty revenues	\$ 107.3	\$ 54.0	\$ 53.3	\$ 245.7	\$ 103.0	\$ 142.7

Table of Contents

Manufacturing fees are earned for the manufacture of products under arrangements with our collaborators when product is shipped to them at an agreed upon price. Royalties are earned on our collaborators' sales of products that incorporate our technologies. Royalties are generally recognized in the period the products are sold by our collaborators.

Under our RISPERDAL CONSTA supply and license agreements with Janssen, we earn manufacturing revenues at 7.5% of Janssen's unit net sales price of RISPERDAL CONSTA and royalty revenues at 2.5% of Janssen's net sales of RISPERDAL CONSTA. The decrease in RISPERDAL CONSTA manufacturing and royalty revenues for the three months ended September 30, 2012, as compared to the three months ended September 30, 2011, was primarily due to a 25% decrease in the quantity shipped to Janssen and a 10% decrease in royalty revenues. The decrease in royalty revenues was due to a decrease in Janssen's end-market sales of RISPERDAL CONSTA from \$390.0 million in the three months ended September 30, 2011 to \$351.0 million during the three months ended September 30, 2012. The decrease in RISPERDAL CONSTA manufacturing and royalty revenues for the six months ended September 30, 2012, as compared to the six months ended September 30, 2011, was primarily due to a 29% decrease in the quantity shipped to Janssen, and an 11% decrease in royalty revenues. The decrease in royalty revenues was due to a decrease in Janssen's end-market sales of RISPERDAL CONSTA from \$793.6 million during the six months ended September 30, 2011 to \$705.8 million during the six months ended September 30, 2012.

We expect revenues from RISPERDAL CONSTA and INVEGA SUSTENNA/XEPLION, our long-acting atypical antipsychotic franchise, to continue to grow, as INVEGA SUSTENNA/XEPLION is launched around the world. Under our INVEGA SUSTENNA/XEPLION agreement with Janssen, we earn royalties on end-market sales of INVEGA SUSTENNA/XEPLION of 5% up to the first \$250 million in calendar-year sales; 7% on calendar-year sales of between \$250 million and \$500 million; and 9% on calendar-year sales exceeding \$500 million. The royalty rate resets at the beginning of each calendar-year to 5%. A number of companies, including us, are working to develop products to treat schizophrenia and/or bipolar disorder that may compete with RISPERDAL CONSTA and INVEGA SUSTENNA/XEPLION. Increased competition may lead to reduced unit sales of RISPERDAL CONSTA and INVEGA SUSTENNA/XEPLION, as well as increasing pricing pressure. Given that RISPERDAL CONSTA is covered by a patent until 2021 in the EU and 2023 in the U.S. and INVEGA SUSTENNA/XEPLION is covered by a patent until 2022 in the EU and 2019 in the U.S., we do not anticipate any generic versions in the near-term for either of these products.

The increase in manufacturing and/or royalty revenues from TRICOR 145, AMPYRA/FAMPYRA, RITALIN LA/FOCALIN XR, INVEGA SUSTENNA/XEPLION, VERELAN and the other manufacturing and royalty revenues for the three and six months ended September 30, 2012, as compared to the three and six months ended September 30, 2011, were due to the addition of the portfolio of commercialized products from the former EDT business. We anticipate manufacturing and royalty revenue erosion in the TRICOR 145 and RITALIN LA/FOCALIN XR franchise for fiscal year 2013 due to the assumed entry of generic competition into the market in late-calendar 2012.

Included in other manufacturing and royalty revenues for the six months ended September 30, 2012 is \$20.0 million of revenue related to the exercise of an option to license certain of our intellectual property, not used in our key clinical development programs or commercial products.

Product Sales, net

Our product sales consist of sales of VIVITROL in the U.S. to wholesalers, specialty distributors and specialty pharmacies. The following table presents the adjustments deducted from VIVITROL product sales, gross to arrive at VIVITROL product sales, net for sales of VIVITROL in the U.S. during the three and six months ended September 30, 2012 and 2011:

Edgar Filing: Alkermes plc. - Form 10-Q

(In millions)	Three Months Ended				Six Months Ended			
	September 30,		September 30,		September 30,		September 30,	
	2012	% of Sales	2011	% of Sales	2012	% of Sales	2011	% of Sales
Product sales, gross	\$ 18.9	100.0%	\$ 13.3	100.0%	\$ 36.6	100.0%	\$ 27.4	100.0%
Adjustments to product sales, gross:								
Medicaid rebates	(1.4)	(7.4)%	(1.0)	(7.5)%	(2.6)	(7.1)%	(2.2)	(8.0)%
Chargebacks	(1.4)	(7.4)%	(1.0)	(7.5)%	(2.7)	(7.4)%	(2.1)	(7.7)%
Product returns (1)	1.4	7.4%		%	0.5	1.4%	(0.7)	(2.6)%
Other	(2.3)	(12.2)%	(1.4)	(10.6)%	(4.2)	(11.5)%	(2.8)	(10.2)%
Total adjustments	(3.7)	(19.6)%	(3.4)	(25.6)%	(9.0)	(24.6)%	(7.8)	(28.5)%
Product sales, net	\$ 15.2	80.4%	\$ 9.9	74.4%	\$ 27.6	(75.4)%	\$ 19.6	71.5%

(1) During the three months ended September 30, 2012, we changed the method by which we recognized revenue on VIVITROL product sales. Prior to August 1, 2012, we did not have sufficient history to reasonably estimate returns related to VIVITROL shipments, and therefore we deferred the recognition of revenue on shipments of VIVITROL until the product left the distribution channel. As we now have sufficient history to reliably estimate returns, we recognize revenue on the sales of VIVITROL upon delivery to our customers and

Table of Contents

provide a reserve for future returns. This change in the method of revenue recognition resulted in a one-time \$1.7 million increase to product sales, net, which was recognized during the three months ended September 30, 2012.

The increase in product sales, gross for the three and six months ended September 30, 2012, as compared to the three and six months ended September 30, 2011, was due to a 42% and 34% increase in the number of units sold, respectively. We expect VIVITROL sales to continue to grow as we continue to penetrate the opioid dependence indication market in the U.S.

We anticipate that Cilag will increase sales of VIVITROL in Russia and the CIS, which are recorded as manufacturing and royalty revenues. In addition, there exists the potential to launch the product in other countries around the world. A number of companies, including us, are working to develop products to treat addiction, including alcohol and opioid dependence, that may compete with VIVITROL, which may negatively impact future sales of VIVITROL. Increased competition may lead to reduced unit sales of VIVITROL, as well as increasing pricing pressure. VIVITROL is covered by a patent that will expire in the U.S. in 2029 and in Europe in 2021 and, as such, we do not anticipate any generic versions of this product in the near-term.

Research and Development Revenue

(In millions)	Three Months Ended September 30,		Change Favorable/ (Unfavorable)	Six Months Ended September 30,		Change Favorable/ (Unfavorable)
	2012	2011		2012	2011	
Research and development revenue	\$ 1.5	\$ 8.1	\$ (6.6)	\$ 2.9	\$ 11.3	\$ (8.4)

R&D revenue is generally earned for services performed and milestones achieved under arrangements with our collaborators. The decrease in R&D revenue for the three and six months ended September 30, 2012, as compared to the three and six months ended September 30, 2011, was primarily due to milestone payments we received during the three and six months ended September 30, 2011. In July 2011, we recognized a \$7.0 million milestone payment earned upon the first sale of BYDUREON in the E.U. and, in April 2011, we recognized a \$3.0 million milestone payment earned upon the receipt of regulatory approval for VIVITROL in Russia for the opioid dependence indication.

Costs and Expenses*Cost of Goods Manufactured and Sold*

(In millions)	Three Months Ended September 30,		Change Favorable/ (Unfavorable)	Six Months Ended September 30,		Change Favorable/ (Unfavorable)
	2012	2011		2012	2011	
Cost of goods manufactured and sold	\$ 41.5	\$ 17.5	\$ (24.0)	\$ 83.6	\$ 33.7	\$ (49.9)

Edgar Filing: Alkermes plc. - Form 10-Q

The increase in cost of goods manufactured and sold in the three months ended September 30, 2012, as compared to the three months ended September 30, 2011, was primarily due to the increase of \$28.3 million in cost of goods manufactured from the addition of EDT's portfolio of commercialized products, partially offset by a \$1.2 million decrease in cost of goods manufactured from RISPERDAL CONSTA. The increase in cost of goods manufactured and sold in the six months ended September 30, 2012, as compared to the six months ended September 30, 2011, was primarily due to the increase of \$58.1 million in cost of goods manufactured from the addition of EDT's portfolio of commercialized products, partially offset by a \$5.9 million decrease in cost of goods manufactured from RISPERDAL CONSTA. The decrease in cost of goods manufactured from RISPERDAL CONSTA in the three and six months ended September 30, 2012, was due to a decrease in the quantity shipped to Janssen.

Research and Development Expense

(In millions)	Three Months Ended September 30,		Change Favorable/ (Unfavorable)		Six Months Ended September 30,		Change Favorable/ (Unfavorable)	
	2012	2011			2012	2011		
Research and development expense	\$ 35.1	\$ 28.2	\$ (6.9)	\$	72.9	\$ 56.2	\$ (16.7)	\$

The increase in R&D expense in the three months ended September 30, 2012, as compared to the three months ended September 30, 2011, was primarily due to a \$4.0 million increase in clinical study activity related to the ALKS 9070 program, which has both phase 3 and phase 1 studies underway, and the addition of \$4.5 million of R&D expense from the former EDT business, partially offset by a \$1.0 million decrease in costs related to the ALKS 37 program. Costs related to the ALKS 37 program decreased as we decided not to advance ALKS 37.

Table of Contents

after the results from the phase 2b multicenter, randomized, double-blind, placebo-controlled, repeat-dose study were announced in May 2012.

The increase in R&D expenses in the six months ended September 30, 2012, as compared to the six months ended September 30, 2011, was primarily due to a \$15.0 million increase in clinical study activity related to the ALKS 9070 program and the addition of \$9.2 million of R&D expense from the former EDT business, partially offset by a \$6.5 million decrease in costs related to the termination of the ALKS 37 program.

A significant portion of our R&D expenses (including laboratory supplies, travel, dues and subscriptions, recruiting costs, temporary help costs, consulting costs and allocable costs such as occupancy and depreciation) are not tracked by project as they benefit multiple projects or our technologies in general. Expenses incurred to purchase specific services from third parties to support our collaborative R&D activities are tracked by project and may be reimbursed to us by our partners. We account for our R&D expenses on a departmental and functional basis in accordance with our budget and management practices.

Selling, General and Administrative Expense

(In millions)	Three Months Ended September 30,		Change Favorable/ (Unfavorable)		Six Months Ended September 30,		Change Favorable/ (Unfavorable)	
	2012	2011			2012	2011		
Selling, general and administrative expense	\$ 31.4	\$ 36.2	\$ 4.8	\$	61.2	\$ 67.7	\$ 6.5	

The decrease in selling, general and administrative (SG&A) expense for the three and six months ended September 30, 2012, as compared to the three and six months ended September 30, 2011, was primarily due to a \$12.2 million and \$20.5 million decrease in professional services expense, respectively, partially offset by the addition of \$5.9 million and \$11.4 million of SG&A costs from the former EDT business, respectively. The decrease in the professional services expense is primarily due to costs incurred in connection with the Business Combination during the three and six months ended September 30, 2011.

Amortization of Acquired Intangible Assets

(In millions)	Three Months Ended September 30,		Change Favorable/ (Unfavorable)		Six Months Ended September 30,		Change Favorable/ (Unfavorable)	
	2012	2011			2012	2011		
Amortization of acquired intangible assets	\$ 10.5	\$ 1.8	\$ (8.7)	\$	21.0	\$ 1.8	\$ (19.2)	

In connection with the Business Combination, we acquired certain amortizable intangible assets, with a fair value of \$643.2 million, which are expected to be amortized over 12 to 13 years. We amortize our amortizable intangible assets using the economic use method, which reflects the pattern that the economic benefits of the intangible assets are consumed as revenue is generated from the underlying patent or contract. Based upon our most recent analysis, over the next five fiscal years we expect the amortization of intangible assets included within our consolidated balance sheet as of September 30, 2012 to be in the range of approximately \$42.0 million to \$70.0 million annually.

Other (Expense), Net

(In millions)	Three Months Ended September 30,				Change Favorable/ (Unfavorable)	Six Months Ended September 30,				Change Favorable/ (Unfavorable)
	2012		2011			2012		2011		
Interest income	\$	0.2	\$	0.4	\$ (0.2)	\$	0.5	\$	0.9	\$ (0.4)
Interest expense		(22.6)		(7.5)	(15.1)		(32.8)		(7.6)	(25.2)
Other income, net		0.7		0.3	0.4		1.6		0.4	1.2
Total other (expense), net	\$	(21.7)	\$	(6.8)	\$ (14.9)	\$	(30.7)	\$	(6.3)	\$ (24.4)

The increase in interest expense for the three and six months ended September 30, 2012, as compared to the three and six months ended September 30, 2011, was primarily due to a \$12.1 million charge we incurred in connection with the Debt Refinancing. Also included in interest expense in the three and six months ended September 30, 2012 is a \$0.6 million charge related to the loss on an interest rate swap. Prior to the Debt Refinancing, our interest rate swap was deemed to be an effective cash flow hedge against the three-month LIBOR rate at which our Term Loans bore interest. In connection with the Debt Refinancing, this cash flow hedge was no longer considered to be effective and we reclassified all previously unrealized losses on the hedge from accumulated other comprehensive (loss) income to interest expense.

Table of Contents

We expect interest expense to decrease beyond fiscal year 2013 due to the Debt Refinancing and as the New Term Loan Facility is paid down.

During the three months ended September 30, 2012, we sold our remaining strategic investment, which was comprised of the common stock of a public company with which we had a collaborative arrangement. This transaction resulted in a realized gain of \$1.2 million which was recorded in Other income, net in the accompanying condensed consolidated statement of operations and comprehensive (loss) income.

Income Tax Provision

(In millions)	Three Months Ended September 30,		Change Favorable/ (Unfavorable)	Six Months Ended September 30,		Change Favorable/ (Unfavorable)
	2012	2011		2012	2011	
Income tax provision	\$ 0.4	\$ 3.7	\$ 3.3	\$ 1.2	\$ 3.6	\$ 2.4

We recorded an income tax provision of \$0.4 million and \$1.2 million for the three and six months ended September 30, 2012, respectively and an income tax provision of \$3.7 million and \$3.6 million for the three and six months ended September 30, 2011, respectively. The tax provision of \$0.4 million and \$1.2 million in the three and six months ended September 30, 2012, respectively, primarily related to foreign taxes on income and was prepared on a discrete quarterly and year-to-date basis as the yearly effective tax rate was not considered a reliable estimate for the current quarter and year-to-date provision. The income tax provision in the three and six months ended September 30, 2011 primarily related to a \$13.2 million current tax expense on the taxable transfer of the BYDUREON intellectual property from the U.S. to Ireland and a deferred tax benefit of \$9.5 million in connection with the Business Combination, as we recorded a U.S. deferred tax liability in purchase accounting allowing for the partial release of an existing valuation allowance.

We record a deferred tax asset or liability based on the difference between the financial statement and tax basis of our assets and liabilities, as measured by enacted jurisdictional tax rates assumed to be in effect when these differences reverse. As of September 30, 2012, we determined, based on the weight of all available evidence, that it is not more likely than not that our remaining U.S. and Irish deferred tax assets will be realized and hence a valuation allowance was recorded on the net deferred tax asset.

Liquidity and Capital Resources

Our financial condition is summarized as follows:

(In millions)	September 30, 2012	March 31, 2012
Cash and cash equivalents	\$ 132.4	\$ 83.6
Investments short-term	67.0	106.8
Investments long-term	8.7	55.7
Total cash, cash equivalents and investments	\$ 208.1	\$ 246.1
Working capital	\$ 286.2	\$ 250.0

Outstanding borrowings	current and long-term	\$	370.6	\$	444.5
------------------------	-----------------------	----	-------	----	-------

		Six Months Ended September 30,	
(In millions)	2012		2011
Cash and cash equivalents, beginning of period	\$	83.6	\$ 38.4
Cash provided by (used in) operating activities		45.0	(15.6)
Cash provided by (used in) investing activities		75.0	(393.0)
Cash (used in) provided by financing activities		(71.2)	459.4
Cash and cash equivalents, end of period	\$	132.4	\$ 89.2

27

Table of Contents

addition of EDT's portfolio of commercialized products, partially offset by an increase in cash used to pay our suppliers and our employees, a \$13.4 million increase in interest payments on our Term Loans and \$5.5 million of payments made in connection with the Debt Refinancing. The increase in payments made to our suppliers and our employees is primarily due to the addition of costs from the former EDT business. In connection with the Debt Refinancing, we incurred a \$2.8 million prepayment penalty, and, as the Term Loans were originally issued at a discount, we allocated \$2.7 million of the total principal repayment to the original issue discount, both of which were classified as operating activities.

The increase in cash flows provided by investing activities in the six months ended September 30, 2012, as compared to the six months ended September 30, 2011, was primarily due to approximately \$500 million of cash used in the purchase of the former EDT business in September 2011. The increase in cash flows used in financing activities in the six months ended September 30, 2012, as compared to the six months ended September 30, 2011, was primarily due to the \$444.1 million of cash received upon the issuance of the Term Loans in September 2011, partially offset by the \$78.0 million of net cash used in the Debt Refinancing that was attributable to financing activities.

Our investments at September 30, 2012 consist of the following:

(In millions)		Amortized Cost		Gains		Gross Unrealized Losses		Estimated Fair Value
Investments	short-term	\$	67.0	\$	0.1	\$		\$ 67.1
Investments	long-term available-for-sale		8.0				(0.5)	7.5
Investments	long-term held-to-maturity		1.2					1.2
Total		\$	76.2	\$	0.1	\$	(0.5)	\$ 75.8

Our investment objectives are, first, to preserve liquidity and conserve capital and, second, to generate investment income. We mitigate credit risk in our cash reserves by maintaining a well-diversified portfolio that limits the amount of investment exposure as to institution, maturity and investment type. However, the value of these securities may be adversely affected by the instability of the global financial markets, which could, in turn, adversely impact our financial position and our overall liquidity. Our available-for-sale investments consist primarily of short and long-term U.S. government and agency debt securities, debt securities issued by foreign agencies and backed by foreign governments, and corporate debt securities. Our held-to-maturity investments consist of investments that are restricted and held as collateral under certain letters of credit related to certain of our lease agreements.

We classify available-for-sale investments in an unrealized loss position, which do not mature within 12 months, as long-term investments. We have the intent and ability to hold these investments until recovery, which may be at maturity, and it is more likely than not that we would not be required to sell these securities before recovery of their amortized cost. At September 30, 2012, we performed an analysis of our investments with unrealized losses for impairment and determined that they are temporarily impaired.

At September 30, 2012 and March 31, 2012, 2% and 7%, respectively, of our investments are valued using unobservable, or Level 3 inputs, to determine fair value as they are not actively trading and fair values could not be derived from quoted market prices. During the six months ended September 30, 2012, the two securities that were included in Level 3 at March 31, 2012 were transferred out of Level 3 as trading in these securities resumed during the period. Also during the six months ended September 30, 2012, there were two investments in corporate debt securities that were transferred from Level 2 to Level 3 as trading in these securities ceased during the period.

Edgar Filing: Alkermes plc. - Form 10-Q

We believe that our current cash and cash equivalents and short- and long-term investments, combined with anticipated revenues, will generate sufficient cash flows to meet our current anticipated liquidity and capital requirements for the foreseeable future.

Borrowings

At September 30, 2012, our borrowings consisted of the New Term Loan Facility, with an outstanding principal balance of \$375.0 million. Please refer to Note 10 *Long-Term Debt* in the accompanying Notes to Condensed Consolidated Financial Statements for a discussion of our outstanding long-term debt.

Table of Contents*Contractual Obligations*

Refer to Part II, Item 7 of our Annual Report in the *Contractual Obligations* section for a discussion of our contractual obligations. With the exception of the effect of the Debt Refinancing, our contractual obligations as of September 30, 2012 were not materially changed from the date of that report.

The New Term Loan Facility has contractual cash obligations as follows:

Contractual Cash Obligations	Total	Less Than One Year (Fiscal 2013)	One to Three Years (Fiscal 2014- 2015)	Three to Five Years (Fiscal 2016- 2017)	More than Five Years (After Fiscal 2018)
Term Loan B-1 - Principal	\$ 300,000	\$ 1,500	\$ 6,000	\$ 6,000	\$ 286,500
Term Loan B-1 - Interest	91,359	6,929	26,629	26,089	31,712
Term Loan B-2 - Principal	75,000	1,875	7,500	65,625	
Term Loan B-2 - Interest	10,890	1,532	5,588	3,770	

Off-Balance Sheet Arrangements

At September 30, 2012, we were not a party to any off-balance sheet arrangements that have, or are reasonably likely to have, a current or future effect on our financial condition, changes in financial condition, revenue or expenses, results of operations, liquidity, capital expenditures or capital resources material to investors.

Critical Accounting Estimates

The discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of our financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results may differ from these estimates under different assumptions or conditions. Refer to *Critical Accounting Estimates* within Part II, Item 7 of our Annual Report for a discussion of our critical accounting estimates.

During the three months ended September 30, 2012, we changed the way in which we recognize revenue on VIVITROL product sales. Prior to the three months ended September 30, 2012, we did not have sufficient history to reasonably estimate returns related to VIVITROL shipments and therefore, we deferred the recognition of revenue on shipments of VIVITROL until the product left the distribution channel. During the three months ended September 30, 2012, we determined that we have sufficient history to reliably estimate returns and we now recognize revenue on the sales of VIVITROL upon delivery to our customers, which is the point in time the buyer assumes the risks and rewards of ownership.

During the period in which we record VIVITROL product sales, we estimate a reserve for future product returns related to those sales. This estimate is based on our historical return rates as well as specifically identified anticipated returns due to known business conditions and product expiry dates. We record the return amounts as a deduction to arrive at our net VIVITROL product sales. Once VIVITROL is returned, it is destroyed. At September 30, 2012, our product return reserve rate is estimated to be 2% of our product sales.

New Accounting Standards

Refer to New Accounting Pronouncements included in Note 2, *Summary of Significant Accounting Policies* in the accompanying Notes to Condensed Consolidated Financial Statements for a discussion of new accounting standards.

Item 3. *Quantitative and Qualitative Disclosures about Market Risk*

Market risks related to our investment portfolio, and the ways we manage such risks, are summarized in Part II, Item 7A, *Quantitative and Qualitative Disclosures About Market Risk* of our Annual Report. We regularly review our marketable securities holdings and shift our investment holdings to those that best meet our investment objectives, which are, first, to preserve liquidity and conserve capital and, second, to generate investment income. Apart from such adjustments to our investment portfolio, there have been no material changes to our market risks during the first six months of fiscal year 2013, and we do not anticipate any near-term changes in the nature of our market risk exposures or in our management's objectives and strategies with respect to managing such exposures.

Table of Contents

We are exposed to foreign currency exchange risk related to manufacturing and royalty revenues we receive on certain of our products as well as certain operating costs arising from expenses and payables at our Irish operations that are settled in Euro. These foreign currency exchange rate risks are summarized in Part II, Item 7A, *Quantitative and Qualitative Disclosures About Market Risk* of our Annual Report. There has been no material change in our assessment of our sensitivity to foreign currency exchange rate risk during the first six months of fiscal year 2013.

Item 4. Controls and Procedures

a) Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act)), at September 30, 2012. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of September 30, 2012 to provide reasonable assurance that the information required to be disclosed by us in the reports that we file under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

b) Change in Internal Control over Financial Reporting

During the period covered by this report, there have been no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may be subject to legal proceedings and claims in the ordinary course of business. For example, we are currently involved in various sets of Paragraph IV litigations in the U.S. and a similar suit in France with respect to certain of our products. We are not aware of any current proceedings or claims that we believe will have, individually or in the aggregate, a material adverse effect on our business, results of operations, cash flows or financial position.

Item 1A. Risk Factors

There have been no material changes from the risk factors disclosed in Part I, Item 1A *Risk Factors*, of our Annual Report.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

On September 16, 2011, our board of directors authorized the continuation of the Alkermes, Inc., program to repurchase up to \$215.0 million of our ordinary shares at the discretion of management from time to time in the open market or through privately negotiated transactions. We did not purchase any shares under this program during the quarter ended September 30, 2012. As of September 30, 2012, we had purchased a total of 8,866,342 shares at a cost of \$114.0 million under this program.

Item 5. Other Information

The Company's policy governing transactions in its securities by its directors, officers and employees permits its officers, directors and employees to enter into trading plans in accordance with Rule 10b5-1 under the Exchange Act. During the quarter ended September 30, 2012, Mr. Floyd E. Bloom, a director of the Company and Ms. Rebecca J. Peterson and Mr. Gordon G. Pugh, each an executive officer of the Company, entered into trading plans in accordance with Rule 10b5-1, and the Company's policy governing transactions in its securities by its directors, officers and employees. The Company undertakes no obligation to update or revise the information provided herein, including for revision or termination of an established trading plan.

Item 6. Exhibits

(a) List of Exhibits:

Edgar Filing: Alkermes plc. - Form 10-Q

Exhibit No.

- 10.1 Employment agreement, dated as of July 30, 2012, by and between Rebecca J. Peterson and Alkermes, Inc. #
- 10.2 Amended and Restated Fiscal 2013 Alkermes plc Affiliated Company Reporting Officer Performance Pay Plan. #
- 10.3 Second Amendment, dated as of August 16, 2012, to the License Agreement, dated as of February 13, 1996, as amended, by and between Alkermes, Inc. (Alkermes) and Janssen Pharmaceutica, Inc. (Janssen US) and the License Agreement, dated as of February 21, 1996, as amended, by and between Alkermes and JPI Pharmaceutica International, a division of Cilag GmbH International (JPI) (Janssen US and JPI together, Janssen), and the Fifth Amendment, dated as of August 16, 2012, to the Manufacturing and Supply Agreement, dated as of August 6, 1997, as amended, by and between Alkermes and Janssen. #
- 10.4 Alkermes plc 2011 Stock Option and Incentive Plan (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on August 6, 2012 and incorporated by reference herein).
- 10.5 Amendment to First Lien Credit Agreement, dated September 25, 2012, among Alkermes, Inc., Alkermes plc, the guarantors party thereto, the lenders party thereto, Morgan Stanley Senior Funding, Inc. as Administrative Agent and Collateral Agent and the arrangers and agents party thereto (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on September 25, 2012 and incorporated by reference herein).
- 31.1 Rule 13a-14(a)/15d-14(a) Certification. #
- 31.2 Rule 13a-14(a)/15d-14(a) Certification. #
- 32.1 Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith).
- 101 The following materials from Alkermes plc's Quarterly Report on Form 10-Q for the quarter ended September 30, 2012, formatted in XBRL (Extensible Business Reporting Language): (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations, (iii) the Condensed Consolidated Statements of Cash Flows, and (iv) the Notes to the Condensed Consolidated Financial Statements (furnished herewith).

Filed herewith.

Table of Contents

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ALKERMES plc

(Registrant)

By: /s/ Richard F. Pops
Chairman and Chief Executive Officer
(Principal Executive Officer)

By: /s/ James M. Frates
Senior Vice President and Chief Financial
Officer
(Principal Financial and Accounting
Officer)

Date: November 1, 2012